# IQVIA Trial Manager

*GCloud 15 Service Definition*

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# IQVIA TRIAL MANAGER SOLUTION

The IQVIA Trial Manager solution is part of a modular research-centric software suite, the IQVIA Health Data Research Platform (HDRP) that provides a wide range of functionality and orchestrated processes for reliable and well documented research support and management. The Trial Manager is made up of a Study Register with Patient-Trial Matching, a Clinical Trial Management System (CTMS) with EDC functionality, and a Trial Budget module. The HDRP platform also offers tools for Biobank Management, a Meta Data Repository, a Raw Data Archive, and a Patient App. Clients can start small, and scale as needed and utilise several API technologies to integrate into existing IT infrastructures (e.g., FHIR, HL7, XML, IHE, CDISC-ODM, OMOP, etc.).

HDRP clients own and host their solutions on hardware of their choice (either on-premises or in the cloud). All data that is collected in the solution belongs to the client. IQVIA will support with Maintenance of the software (e.g., by provisioning bugfixes) and provide support on how to backup, restore, and implement disaster recovery plans. The Biobanking solution can run on MSSQL, Oracle, or PostgreSQL databases. These belong to the client and can be freely accessed upon exit. The solution can also be implemented with an XML/REST interface that allows import and export of all relevant data from the solution.

### Background & Philosophy

HDRP solutions have been on the market for over fifteen years. In 2008, HDRP was created by a spinoff of the Charité University Medicine in Berlin, one of the largest university hospitals in Europe. It was clear the current state of clinical research was far from where it should be, and the HDRP team wanted to do its part to help create a paradigm shift towards personalised medicine.

The initial focus began with supporting biobanks in their day-to-day operations. The resulting IQVIA Biobanking solution includes the ability to ingest legacy data from systems that need to be retired, as well as the API technology to establish a data integration platform for all data relevant to the biospecimens and their donors. User friendly workflows for manual data capture around all processes relevant to a biobank (incl. storage, processing, shipment, etc.) rounds off the Biobanking solution.

However, researchers needed solutions to do more in their day to day. Biospecimen are often collected for clinical trials. Hence the HDRP platform was continuously built out to offer value in the space of study management, including patient identification for clinical trials, as well as a full clinical trial management system with EDC capabilities. All clinical data that can be pulled into the HDRP core system can be used to identify potential candidates more quickly for clinical trials, which can be set up in the Trial Manager solution with structured inclusion and exclusion criteria (e.g., age, diagnoses, medication, lab values, etc.). But the workflow does not end with identifying candidates. Principal investigators can use the Trial Manager solution to design screenings and the actual clinical trials with user friendly forms designers. All eCRFs in the system can be prepopulated with source data, reducing time needed for data collection. Project budgets can be documented, and invoices linked to project


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milestones (e.g., completion of patient visits) are tracked, making sure that projects stay within projected budgets. All data collected in projects can be queried after completion of the project and remain within the patient's longitudinal record for future use (e.g., identifying the same patients for future trials). The platform comes with a patient portal that allows patients to log in, verify their data, provide questionnaire data themselves (ePROs), view upcoming appointments, etc.

HDRP system architecture also allows for flexibility with the integration of workflow and reporting engines that make it possible to map out client-specific standard operating procedures (SOPs) into system-driven, highly customised workflows that can be executed by end users with appropriate access rights. Furthermore, IQVIA offers trainings to its clients' IT personnel to allow them to develop these components themselves. The same goes for the ability to access available APIs (XML/REST) to build new interfaces, as well as best practices on how to back up the database, test disaster recovery, manage access rights settings, and much more.

The HDRP team has continued to build out module extensions to create synergies. These modules include a Meta Data Repository, a Raw Data Archive, an OMOP Pipeline, and a Patient App.

HDRP was built in Germany and has a proven track record, currently installed in 32 of 38 university hospitals in Germany, 4 out of 6 Health Centers. Over the last decade, IQVIA has further expanded in Europe with HDRP solutions, which are currently in use in Austria, Switzerland, Slovenia, UK, Italy, Czech Republic, Spain, and North America (Canada, and United States).

**Overview of Features and Benefits**

### Extract of Key Features:

- Aggregation of relevant source data into longitudinal patient/donor records (e.g., therapeutic, and diagnostic events).
- User-friendly, high-quality data collection workflows regarding relevant research data
- Consent tracking
- Query interface for quick/complex searches of patient cohorts
- Study Register with inclusion and exclusion criteria management
- User management (incl. detailed rights & roles management)
- Pseudonymisation algorithms
- Configurable forms designer (e.g., eCRFs with source data pre-population)
- Data monitoring
- SAE tracking
- Trial budget definition
- Invoice tracking (e.g., for milestone related work)


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## Extract of Key Benefits:

- Improve collaboration across departments with one centralised research management system.
- Reduce time needed for identifying patient cohorts for research projects.
- Reduce time needed for data collection.
- Keep track of studies that are at risk at exceeding budget
- Enhance research data pipeline by harmonising biobank and study solution with one tool.
- More easily comply with regulations (e.g., by linking consent data to patient records).
- Orchestrate/parallelise processes to improve productivity with integrated workflow engine.


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